

Roadmap to a Cure:

Determining Benefits of Treatment

by Craig W. Newman, Ph.D.

In 2005, the American Tinnitus Association (ATA) developed a Roadmap to a Cure for tinnitus. The Roadmap provides direction to researchers by helping them identify key areas that require scientific exploration. The ultimate goal is a cure for tinnitus.

The Roadmap includes a sequence of four different pathways. Paths A and B focus on “where” and “how” tinnitus is generated in the auditory system. Paths C and D relate to “developing” and “optimizing or customizing” tinnitus treatments. A component of the Roadmap includes the need to determine treatment benefits. The following will address this important issue and ways in which treatment benefits can be measured.

Why is it important to measure treatment benefit?

Over the past two decades we have witnessed an increase in efforts by researchers and clinicians to develop effective tinnitus therapies. Once developed, careful measurement of a patient's progress with these treatments is important in order to determine if they are successful or not. That is, measuring or quantifying treatment benefit allows both the researcher and clinician to learn which practices, procedures, and devices provide the greatest amount of tinnitus relief.

Evaluating benefit helps to answer important questions about the *treatment effectiveness* of a specific therapy (such as, “Does the herb *Ginkgo biloba* reduce the loudness of tinnitus?”) and *treatment efficiency* where two or more specific treatment options are compared (such as, “Is tinnitus masking as effective as tinnitus habituation therapy after one year of treatment?”). Furthermore, determining tinnitus treatment benefit is critical in demonstrating to insurance companies the clinical effectiveness of existing therapies and new ones on the

horizon. This is known as *cost-effectiveness* and is an important consideration for third-party payers when making decisions about reimbursement.

In essence, evaluating treatment benefit reveals what works and what doesn't work. Without that information, selecting the most appropriate tinnitus therapy for a given individual is based on trial-and-error, practitioners' opinions, and clinical impressions. The need to measure benefit for specific treatments is in keeping with the current trend that emphasizes “evidence-based” clinical practice.

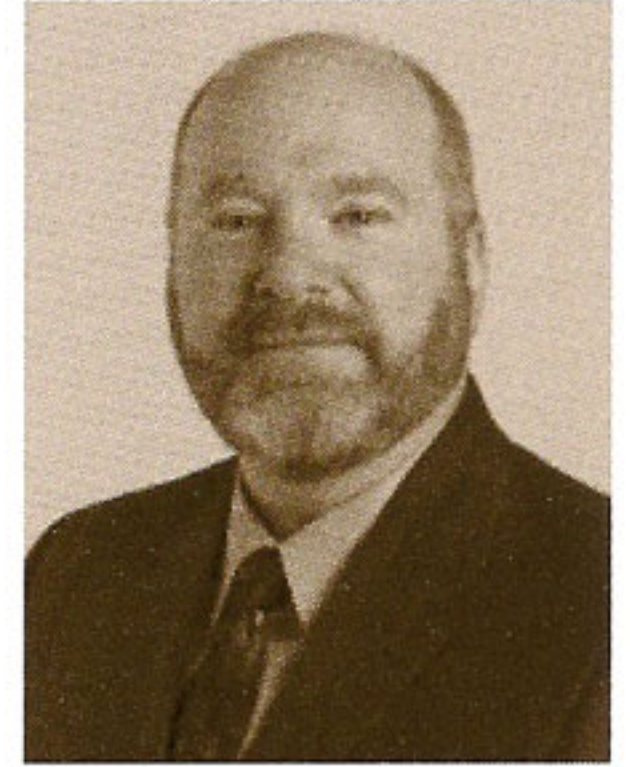
How do we measure benefit?

Treatment benefit could be determined by evaluating changes in tinnitus loudness and pitch before and after treatment. However, since we already know that the tinnitus loudness and pitch do not necessarily reflect the degree of tinnitus annoyance, this may not be the best way to determine a treatment's benefit.

We are more interested in assessing how a specific tinnitus therapy ultimately affects a person's quality of life. Therefore, measuring tinnitus *disability, activity limitation, handicap, and participation restriction* would be good indicators of treatment success. These components (borrowed from the World Health Organization's International Classification of Functioning, Disability, and Health) look at the degree to which tinnitus influences routine abilities (such as falling asleep or concentrating) and everyday life (such as relationships with family, friends, and coworkers).

Scientists agree that the best way to evaluate disability and handicap is to administer a standardized tinnitus questionnaire. This questionnaire, or *tool* as we call it, makes it possible to determine the impact of a treatment (whether it is medical, surgical, or rehabilitative) by

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comparing scores on a questionnaire obtained before, during, and after treatment. For example, a reduction in tinnitus disability and handicap (which may or may not be accompanied by a change in tinnitus loudness), is likely a reflection of the benefit patients may receive from that particular treatment approach. On the other hand, if after receiving treatment there is no change or there's an increase in disability or handicap, this suggests that the treatment is not providing sufficient benefit, and additional or alternative treatments should be considered.

Are there tools that can determine treatment benefit?

There are a number of excellent tinnitus questionnaires that can be used to evaluate the benefits of treatment. Before being considered for clinical use to determine treatment benefit, the questionnaire must have good *test-retest reliability*. Test-retest reliability ensures that changes in questionnaire scores truly reflect changes in the person's quality of life due to the treatment itself. Currently, there are at least 10 commonly used tinnitus questionnaires that evaluate tinnitus distress, disability, handicap, coping styles, and strategies.

The primary questionnaire we use in our clinic to determine treatment benefit is called the "Tinnitus Handicap Inventory" or THI. The THI is a 25-item questionnaire that evaluates the impact of tinnitus on everyday life and the emotional reactions to tinnitus. The table shows some examples of the questions on the THI.

Table 1.

Because of your tinnitus, is it difficult for you to concentrate?

Yes Sometimes No

Does your tinnitus make you feel angry?

Yes Sometimes No

Because of your tinnitus, do you have trouble falling to sleep at night?

Yes Sometimes No

Do you feel as though you cannot escape your tinnitus?

Yes Sometimes No

Does your tinnitus interfere with your job or household responsibilities?

Yes Sometimes No

Example items from the Tinnitus Handicap Inventory (Newman, Jacobson & Spitzer, 1996)

As shown, patients respond to each question by circling a "yes" (4 points), "sometimes" (2 points) or "no" (0 points). The responses are summed, with the total score ranging from 0 to 100 points. Higher scores represent greater tinnitus handicap. The THI can be administered before and after any tinnitus treatment. A clinically significant change in perceived tinnitus handicap occurs when there is a 20-point or greater difference before and after treatment. In other words, a change of 20 points or more shows that the treatment is truly providing help for the patient.

There are several other tools that could be used to evaluate benefit, including the "Tinnitus Handicap Questionnaire" and the "Tinnitus Reaction Questionnaire." Currently, a new questionnaire, called the "Tinnitus Functional Inventory," is being developed by Dr. Mary Meikle at the Oregon Health & Science University and her colleagues in Oregon, Florida, and Ohio. This new tool is designed to combine the best features of existing questionnaires. Hopefully it will be used as the standard measure across all clinical settings in the U.S. to evaluate the effectiveness of tinnitus treatments.

An Example

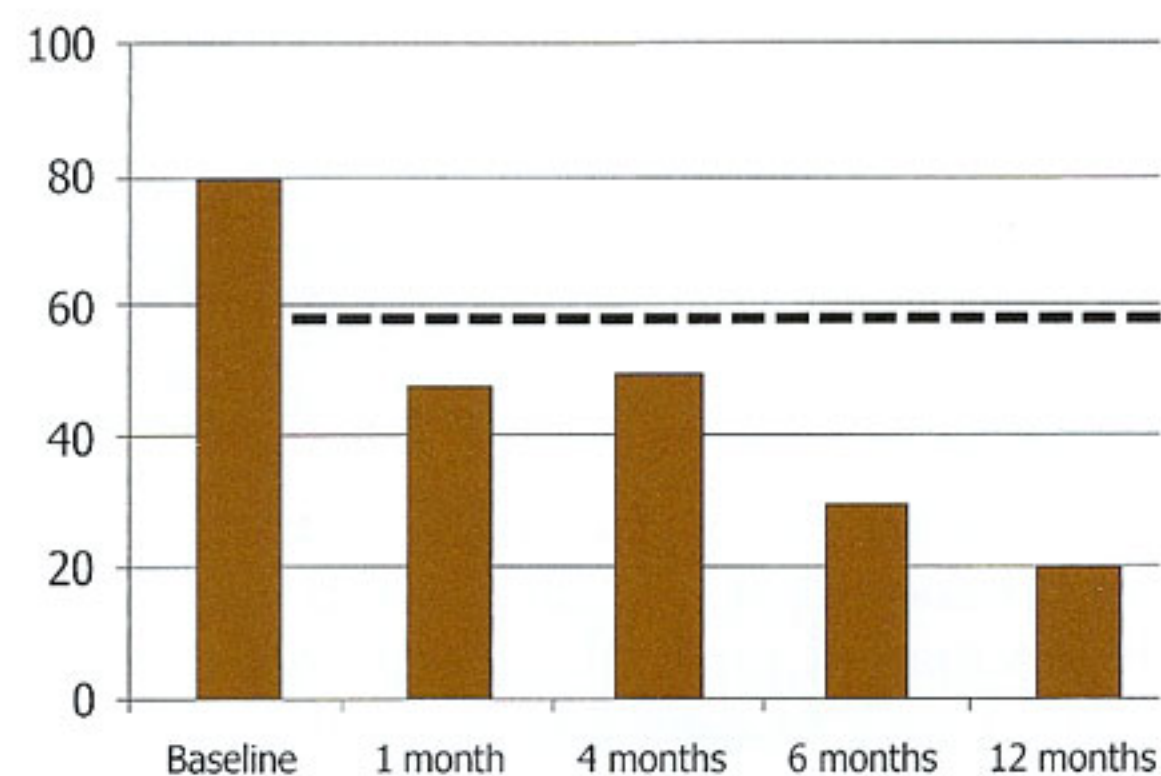
Recently, we've begun to offer a new sound therapy called *Neuromonics Tinnitus Treatment*. In this treatment, which originated in Australia, a pleasant acoustic signal (embedded in music) is delivered through high-fidelity earphones at a comfortable listening level. The course of the treatment program is approximately six months followed by a maintenance phase, which is simply an ongoing use of the Neuromonics device whenever the patient feels that it's needed. It can be used once a week or once a month. It's very individual.

Although the treatment has been studied for several years in Australia, we felt it was important to demonstrate to both our patients and ourselves the benefits of this newly introduced sound therapy in the U.S. We decided to

administer the THI before treatment began to get a baseline measure. After that, we re-administered the THI several times during the treatment program.

The bar graph illustrates the benefit derived from the treatment for one of our patients. Any score falling below the dashed line represents a significant reduction in tinnitus handicap, or conversely an improvement in quality of life.

Figure 1.



Bar graph shows the benefit from Neuromonics for one patient over a one-year period. Scores on the Tinnitus Handicap Inventory falling below the dashed line indicate improvement in quality of life.

As shown in the graph, Neuromonics provided benefit for this particular patient as early as one month, and has continued to help over the course of one year. We are currently monitoring all of our patients with a variety of tinnitus questionnaires in order to evaluate the benefits of the Neuromonics treatment, as well as the other therapy options we provide.

Conclusion

Several treatment approaches are offered by practitioners all in an attempt to help provide relief from the annoyance of tinnitus. These treatments include a wide range of sound therapies, cognitive behavioral therapy, support and education groups, stress management, drug therapy, and alternative treatments such as herbal remedies.

In the past, the effectiveness of many treatment options was based on faith rather than scientific proof. The use of standardized tinnitus questionnaires provides an avenue to measure changes in tinnitus handicap and disability resulting from intervention in a scientific manner. These measures reflect the impact of tinnitus treatments on the person's quality of life. It is the responsibility of the researchers and practicing clinicians to measure treatment benefit for existing options and as well as new alternatives as they emerge. In this way, people with tinnitus can make an informed decision about which treatment options are most beneficial for their lifestyle and needs.

ATA's *Roadmap to a Cure* provides direction to researchers and clinicians in establishing new and effective therapies. It is our responsibility as scientists and tinnitus clinicians to provide evidence that these new options will be beneficial in providing tinnitus relief. ☒

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